

PATENT APPLICATION
Docket No.: 301489.3003-100
Prior Docket No.: (MIT-6186Z)

UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Michael S. Feld and Joseph Baraga
Application No.: 08/745,509 Filed Date: November 12, 1996
Confirmation No. 6390 Group: 3737 Examiner: R. Smith
For: A Raman Endoscope

CERTIFICATE OF MAILING	
I Herby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, Washington, D.C. 20231	
on _____ Date	_____ Signature
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DECLARATION OF STEPHEN F. FULGHUM

Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Stephen F. Fulghum, hereby declare that:

- 1) I am employed by Newton Laboratories, Inc. and a copy of my biographical history including a list of publications is attached as Exhibit A. I have about 34 years of experience in building laser systems and developing applications including the design and development of endoscope systems to detect endogenous fluorescence of tissue. I am the named inventor of U.S. Patent No. 6,364,829.
- 2) That I have read the application and claims of U.S. Patent Application Serial No. 08/745,509 (the '509 application) filed on November 12, 1996, a copy of which is attached as Exhibit B, and entitled "Raman Endoscope" and am therefore familiar with the contents thereof.

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- 3) I have read and am familiar with the following documents that have been cited during the examination of the '509 application:

Alfano et al.	5,293,872
Lewis et al.	5,377,003
Ito	5,305,736
Nagasaki et al.	4,653,478
Sekiguchi	4,821,117

- 4) The '509 application describes and illustrates in connection with Figures 1 and 4 the use of an endoscope having a distally mounted sensor array or imaging device for endogenous fluorescence or Raman measurements. The '509 application specifically references fluorescence measurements of tissue in the background at page 2 of the specification, again at page 4 and is described in detail in U.S. Patent No. 5,125,404 incorporated by reference at page 15, lines 9-15. The '509 application describes and illustrates all of the structural elements needed to perform fluorescence measurements of tissue using such a system, namely,
- a) a sensor array mounted on the distal end of an endoscope;
 - b) a filter placed in front of the sensor array;
 - c) a lens to collect light at the distal end of the endoscope for detection by the sensor array;
 - d) a fiber optic cable extending through the endoscope that is coupled at its proximal end to a radiation source to illuminate tissue at the distal end of the endoscope; and
 - e) a computer memory for storing the representation of the tissue.
- 5) The '509 application described the use of sensing arrays or detectors that are distally mounted on an endoscope in sufficient detail such that I would be able to build and use a device based on the description. The filter at the distal end of the device used for fluorescence imaging can employ a cutoff filter to remove the

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source wavelengths back-scattered towards the detector. This is described, for example, at Column 21, lines 56-58 of U.S. Patent No. 5,125,404 which was incorporated into the application by reference at page 15 of the specification. The filters described in connection with Ito and Nagasaki references are not suitable for fluorescence imaging. The filter 10c in Figure 3 of Ito is for a YAG laser, which is frequently used in photodynamic therapy, emits in the infrared and is not suitable for fluorescence or Raman imaging. The filter 4 in Figure 1 of Nagasaki is a tricolor filter used to generate a standard color image and is not suited for fluorescence or Raman imaging. These references fail to disclose or suggest filtering suitable for the claimed invention.

- 6) Additionally, at the time of the original filing of this application on October 29, 1993, endoscope systems being used for fluorescence or Raman imaging typically sought to use two detectors outside of the endoscope, one to provide a normal image and one for fluorescence. These systems also typically used different filters outside of the endoscope to collect light in different portions of the spectrum. At that time, it was difficult or impossible to fit these components into the distal volume available in an endoscope. To construct a system using a single distally positioned sensor with a small adjustable filter or a single filter was consequently not apparent to those constructing endoscopes at the time. Additionally, issues resulting from cost and regulatory factors also tended to deter consideration of such a dedicated design.

All statements made herein on my own knowledge are true and all statements made on information and belief are believed to be true. I have further been warned that willful false statements and the like are punishable by fine or imprisonment, or both pursuant to 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

11 APRIL 2003

Date

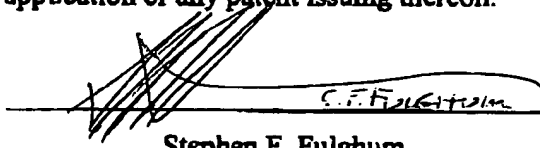

Stephen F. Fulghum

EXHIBIT A

NAME		POSITION TITLE	
Dr. Stephen F. Fulghum, Jr.		Vice President, Technology	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
Washington and Lee University, Lexington, VA	B.S.	1969	Physics
Massachusetts Institute of Tech., Cambridge MA.	PhD	1979	Physics

NOTE: The Biographical Sketch may not exceed four pages. Items A and B (together) may not exceed two of the four-page limit. Follow the formats and instructions on the attached sample.

Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

Washington and Lee University, Lexington, VA Student (1965-1969) B.S. in Physics, magna cum laude, Phi Beta Kappa.

US Army Strategic Communications Command, Ft. Huachuca, AZ First Lieutenant, Training (1969-1970), U.S. Army Infantry School OCS (2nd in class 1971), Advanced Concepts Office (1971-1973) Analyzed future role of fiber optics in Army communications.

Massachusetts Institute of Technology, Cambridge MA. Graduate Student (1973-1979) Advisors: Professors Ali Javan and Michael Feld.

Avco Everett Research Laboratory, Everett, MA Research Scientist (1979-1987)

Science Research Laboratory, Somerville, MA Principal Research Scientist (1987-2000)

Newton Laboratories, Inc., Woburn, MA Vice President, Technology (1996-present)

Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.

(1) S.F. Fulghum and J.J. Burke, "Optical Fiber Links for Telecommunications," Advanced Concepts Office, USASTRATCOM, Ft. Huachuca, AZ (1972)

(2) R.E. McNair, S.F. Fulghum, G.W. Flynn, M.S. Feld and B. J. Feldman, "Energy Storage and Vibrational Heating in CH₃F Following Intense Laser Excitation," Chem. Phys. Lett. 48 (2) 241-244 (1977)

(3) S.F. Fulghum, I.P. Herman, M.S. Feld and A. Javan, "XeF ground state dynamics in a laser discharge," Appl. Phys. Lett. 33 (11) 926-928 (1978)

(4) S.F. Fulghum, M.S. Feld and A. Javan, "XeF Ground State Dissociation and Vibrational Equilibrium," Appl. Phys. Lett. 35 (3) 247-249 (1979)

(5) R.A. Forber, R.E. McNair, S.F. Fulghum, M.S. Feld and B.J. Feldman, "Collision-induced energy absorption and vibrational excitation by intense laser radiation in CH₃F," J. Chem. Phys. 72 (9) 4693-4712 (1980)

(6) S.F. Fulghum, M.S. Feld and A. Javan, "A Multilevel Model of XeF Ground State Kinetics," IEEE J. Quantum Electron. QE-16 (8) 815-820 (1980)

(7) E. Sabar, C. Kittrel, S.F. Fulghum, M. Feld and S. Latt, Sister-chromatid Exchange Induction in Chinese Hamster Ovary Cells by 8-methoxypsoralen and Brief Pulses of Laser Light," Mutation Research, 83 (91) (1981)

EXHIBIT A

- (8) S.F. Fulghum, D.W. Trainor, C. Duzy and H. Hyman, "Stimulated Raman Scattering of XeF^{*} Laser Radiation in H₂- Part II," IEEE J. Quantum Electron. QE-20 (3) 218-222 (1984)
- (9) S.F. Fulghum, D. Klimek, A. Flusberg, D.W. Trainor, C. Duzy, H. Hyman, J.D. Daugherty and D. Korff, "Stokes phase preservation during Raman amplification," J. Opt. Soc. Am. B, 3 (10) 1448-1459 (1986)
- (10) C. Londono, M.J. Smith, D.W. Trainor, R. Berggren, S.F. Fulghum and I. Itzkan, "Detailed Optical Characterization of a Near Diffraction Limited Xenon Fluoride Laser," IEEE J. Quantum Electron. QE-24 (12) 2467-2476 (1986)
- (11) S.F. Fulghum, D.W. Trainor and C.H. Appel, "Transient Refractive Index Measurements in XeF Laser Gas Mixtures," IEEE J. Quantum Electron. QE-25 (5) 955-962 (1989)
- (12) A. Mandel, R. Holmes, A. Flusberg, S.F. Fulghum and D. Angeley, "High-gain, high-efficiency stimulated Raman amplification with beam clean up," J. Appl. Phys. 66, 4625-4634 (1989)
- (13) A. Flusberg, S.F. Fulghum, H. Lotem, M. Rockni and M. Tekula, "Multiseed stimulated Raman scattering for wave-front control," J. Opt. Soc. Am. B, 18, 1851-1875 (1991)
- (14) S.F. Fulghum and M. Tilleman, "Interferometric calorimeter for the measurement of water-vapor absorption," J. Opt. Soc. Am. B, 8 (12) 2401-2413 (1991)
- (15) A. Flusberg and S. F. Fulghum, "Detectivity of shot-noise-limited interferometric systems measuring weak gaseous absorption," Opt. Eng. 35 (6) 1761-1771 (1996)
- (16) B.V. Weber and S.F. Fulghum, "A high-sensitivity, two-color interferometer for pulsed power plasmas," Rev. Sci. Instrum. (spring 1997)

Newton Laboratories, Woburn, MA

Responsible for the design and fabrication of a fiberoptic, point contact spectrofluorimeter and an imaging spectrofluorimeter, now in engineering development for production.

Science Research Laboratory, Somerville, MA

Principal Research Scientist (1987-2000) Developed a laser interferometric calorimeter to measure atmospheric absorption coefficients down to 10^{-10} cm^{-1} . This work received the LASERS '89 Award as "an original and timely contribution to the field of lasers and applications". Designed and delivered an ultrasensitive, two-color, laser interferometer to the Naval Research Laboratory under a Phase II SBIR to simultaneously measure both electron density and neutral gases in high power, pulsed plasma switches. Designed and delivered a high-frequency optical correlator to the NASA Lewis Research Center under a Phase II SBIR to measure the velocity of rocket engine exhaust streams. Designed and delivered a Sagnac interferometer to the MIT Lincoln Laboratory to measure absorption in optical materials at 193 nm.
